Telefax Transmittal
Cover sheet

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966
(302) 934-8051

June 15, 2004

25...pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
Examiner P. Baskar	USPTO Group Art Unit: 1645	703-872-9306

PERSON FROM:	COMPANY/DEPT FROM:	FAX NUMBER:
Diane Payne on behalf of William M. Blackstone	Intervet, Millsboro Patent Department	302-934-4305

RE: USSN: 10/034,500

Attorney Docket No.: O-2000.605 US

Please accept the documents, which follow in the above-identified application.

Supplemental Response (9 pages)
Petition for Extension of Time (1 pages)
Notice of Appeal (1 pages)
35 U.S.C. 112, first paragraph and the Wands Analysis Power Point Presentation (12 pages)
Certificate of Facsimile Transmission (1 page)

intervet

Certificate of Facsimile Transmission

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on June 15 2004.
Date


Signature

Diane Payne
Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Supplemental Response (9 pages)
Petition for Extension of Time (1 pages)
Notice of Appeal (1 pages)
35 U.S.C. 112, first paragraph and the Wands Analysis Power Point Presentation (12 pages)
Certificate of Facsimile Transmission (1 page)

Attorney Docket Number O-2000.605 US

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

By: Diana Coyne

Date: 6-15-04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:
Jacobs et al

Serial Number: 10/034,500 Group Art Unit: 1645

Filed: December 20, 2001 Examiner: P. Baskar

For: LAWSONIA INTRACELLULARIS VACCINE

Corresponding to: EP 00204660.5, filed December 20, 2000

SUPPLEMENTAL RESPONSE

Honorable Commissioner of Patents June 15, 2004
Alexandria, VA 22313

Sir:

Further to the remarks submitted with the Amendment and Response to Final Office Action Issued February 18, 2004, filed May 18, 2004, applicants wish to submit these additional comments with respect to the rejections under 35 U.S.C. 112, first paragraph, for the Examiner's consideration.

The Examiner has pointed out that "[t]he claims are drawn to an isolated *Lawsonia intracellularis* outer membrane protein and immunogenic composition comprising an amino acid sequence homologous to SEQ. ID. NO: 2 being immunoreactive with antisera to SEQ ID NO: 2 and having molecular weight of about 37 KD, said outer membrane protein being obtainable by a process comprising the steps of

a) subjecting an outer membrane preparation to SDS-PAGE and

b) excision of the 37 KD band from the gel, and an immunogenic fragment of said protein."

The Examiner has rejected the claims under 37 CFR 112, first paragraph. The Examiner commented that "[t]he actual structure or other relevant identifying characteristics of each protein...having the claimed properties of the 37 kD protein can only be determined empirically by actually making every nucleic acid that encodes the recited variability and testing each to determine whether such a protein has the particularly disclosed properties of an 37kD protein. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonably predict the

complete structure of the claimed invention from its function. This specification does not teach such, and the art is devoid of this correlation for SEQ ID NO: 2, 37kD protein with undetermined function. There is no written description support for homologous protein or fragments of SEQ ID NO 2 as claimed."

In the Amendment filed May 18, 2004, claim 9, the independent claim has been amended to recite:

> 9. An isolated *Lawsonia intracellularis* outer membrane protein, said protein being immunoreactive with antisera to SEQ ID NO: 2 and having a molecular weight of about 37 kD.

As amended, the claimed protein must be an outer membrane protein found in Lawsonia intracellularis that has a molecular weight of about 37kD, which in the specification is taught to be measured by SDS-PAGE, and is immunoreactive with the antisera to the protein of SEQ ID NO: 2.

Using the method provided by applicants for isolating outer membrane proteins from any Lawsonia intracellularis, any skilled practitioner can identify a protein of about 37kD, if present, excise it, and determine its immunoreactivity to antisera to SEQ ID No:2, also using the methods provided in present specification and examples. The invention is fully described and enabled such that the

skilled practitioner can make the invention and, for that purpose, immunoreactivity is a defining function that can easily be tested within the skill in the art. Moreover, the function of the claimed 37kD protein is also described in the specification as being immunogenic.

Considering the WANDS analysis of 35 U.S.C. 112, first paragraph [In re Wands, 8 USPQ2d1400(Fed.Cir.1988)] presented by Remy Yucel, SPE of Group 1636 on April 27, 2004 at the Biotechnology, Chemical and Pharmaceutical Customer Partnership meeting, it is respectfully submitted that the amended claim meets all the requirements of the statue. A copy of the Power Point presentation is enclosed for the Examiner's convenience.

Analyzing the present invention with respect to the "WANDS Factors," it is believed that the present specification claims meet all the requirements:

I. The nature of the invention: The invention is an isolated protein that can be obtained by methods disclosed in the present specification from a Lawsonia intracellularis outer membrane having a molecular weight of about 37kD, as measured by a defined method, and having a defined antiserum immunoreativity.

II. The state of the prior art: The prior art teaches Lawsonia intracellularis isolates, and methods for obtaining them. It also teaches isolated Lawsonia intracellularis outer membrane proteins, but none having the molecular weight of about 37kD.

III. The predictability or lack thereof in the art: All Lawsonia intracellularis isolates will have outer membrane proteins and, following the methods provided in this specification, it can be determined with certainty whether or not they contain a 37kD protein. If they do, it is taught how to determine whether the 37kD protein is immunoreactive with antisera to SEQ ID No: 2 as defined in the specification. Accordingly, obtaining and determining whether a particular strain contains proteins according to the invention is completely predictable for the skilled practitioner. Furthermore, in the paragraph bridging pages 9 and 10 of the specification, the well known variations in amino acid sequences resulting from deletions, substitutions, insertions, inversions or additions of amino acids is discussed. As established by the cited references, they are well known in the art. Furthermore, specific replacements and substitutions

of amino acids occurring frequently in evolution are disclosed and discussed. Such conventional changes in sequences are also, therefore, predictable.

IV. The amount of direction or guidance present:

Example 1, beginning on page 20 of the specification, teaches obtaining Lawsonia intracellularis bacteria from infected pigs and the method for obtaining isolated bacteria. It is further specifically described how to obtain outer membrane protein preparations, as well as how to produce antisera in rabbits. Moreover, amplification of the outer membrane protein genes is also taught. Based on the information provided in this example, the ordinary practitioner is able to isolate and disrupt the bacteria, isolate the outer membrane proteins according to their molecular weight, produce antisera to any desired protein, and determine whether there is immunoreactivity between any of the isolated proteins and antisera. The ordinary practitioner is fully enabled to practice the present invention without experimentation. The only unknown could be whether a particular isolate contained a protein having a molecular weight of about 37kD and, if so, whether such an outer

membrane protein, is reactive with antiserum to the specific amino acid in SEQ ID No 2. Determining these answers is not experimentation, it is testing because each of the required procedures is provided and exemplified in the specification.

V. The presence or absence of working examples: Examples are provided, as discussed above.

VI. The breadth of the claims: The claims, as amended, are limited to isolated Lawsonia intracellularis outer membrane proteins having a defined molecular weight and a defined immunoreactivity.

VII. The relative skill of those in the art: The relative skill of those practicing the technology is relatively high and, with the information provided in the specification, they can easily isolate particular Lawsonia intracellularis outer membrane proteins and test them to determine whether or not they are within the scope of the claims.

VIII. The quantity of experimentation needed: As discussed above, the efforts of the skilled practitioner in the laboratory with respect to the claimed invention constitute testing rather than experimentation. There is no empirical experimentation required.

Reviewing the Wands Factors, it is noted that in the present case all of the elements of the Wands analysis have been met even though, as presented in the Power Points, it is not always necessary to satisfy every factor in every case for a conclusion that the requirements of 35 U.S.C. 112, first paragraph, have been met.

Applicants, by their description of the steps for obtaining an isolated Lawsonia intracellularis outer membrane protein, and for testing its immunoreactivity, preclude the need for any experimentation. Following the teachings in the specification, any strain can be isolated from diseased swine, an outer membrane protein preparation formulated, the 37kD sequence isolated and, after separately producing antiserum to the SEQ ID No: 2 protein, any outer membrane protein of about 37kD present can be tested to determine whether or not it is within the scope of the claimed invention. Applicants possess the invention to the full scope of the present claims and enable any skilled practitioner in the art to do the same. Presently claimed is an isolated outer membrane protein of a particular size, obtained from a specific organism's

outer membrane having defined immunoreactive characteristics.

In view of the above it is believed that claims 9, 13, 18-21 and 38 are in condition for allowance.

Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, she is invited to telephone applicant's attorney at the number below.

Respectfully Submitted,

William M. Blackstone
Attorney for Applicants
Registration No. 29,772

Akzo Nobel Pharma Patent Department
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966
Tel: (410) 464-0581
Sec: (302) 934-4327
Fax: (302) 934-4305